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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SMITH, TERRI L	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 08/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,426	REGHABI ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1-30-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1–43 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 3, 4, 6, 8, 9, 12, 26, 28, 30, 31, 42, 49, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulman et al., U.S. Patent 6,164,284.

4. Regarding claims 1, 26, and 42, Schulman et al. disclose implanting an implantable sensor at a single site in a patient (Fig. 1, element 100c), an implantable sensor having a housing within which are disposed a plurality of implantable sensing elements (column 4, lines 29–30), each sensing element is operable through electrical communication with an external controller via an individual interconnect (Figs. 2 and 3A; elements 172, 174; column 7, lines 30–31; column 15, lines 14 –16); and reading an output from at least one of the implantable sensing elements (column 4, lines 66–68), wherein a plurality of parameters are read from an implantable sensor at a single site (column 4, lines 66–68; column 7, lines 30–32), and wherein an output read from at least one of the implantable sensing elements is a quantifiable value (column 4, lines 24–25); evaluating a patient based on an output read from at least one implantable sensing

element (column 4, lines 62–64); each of a plurality of implantable sensing elements comprises a power supply (column 15, lines 5–7).

5. Schulman et al. disclose at least one of the implantable sensing elements is a biological parameter sensor (claim 2), physiological parameter sensor (claim 3), and an analyte sensor (claim 4) (column 4, lines 22–25); reading an output from at least one of the implantable sensing elements comprises reading an output from an implantable sensing element that responds to blood oxygen saturation (claims 6 and 28), glucose (claims 8 and 30), and temperature (claims 9 and 31) (column 7, lines 30–33); administering therapy to the patient based on an output read from at least one implantable sensing element (claim 12) (column 2, lines 52–56); an interconnect between each sensing element and the external controller does not pass through another sensing element (claims 49–50) (Figs. 2 and 3A).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 5, 7, 10, 11, 13–25, 27, 29, 32–41, and 43–48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al., U.S. Patent 6,164,284.

9. Regarding claim 43, Schulman et al. disclose implanting an implantable sensor at a single site in a patient in the field (Fig. 1, element 100c), an implantable sensor having a housing within which are disposed a plurality of implantable sensing elements (column 4, lines 29–30); and reading an output from at least one of the implantable sensing elements (column 4, lines 66–68), wherein a plurality of parameters are read from an implantable sensor at a single site (column 4, lines 66–68; column 7, lines 30–32), and wherein an output read from at least one of the implantable sensing elements is a quantifiable value (column 4, lines 24–25), and a plurality of implantable sensing elements comprises a blood oxygen saturation sensing element measuring a parameter for blood oxygen level (column 7, lines 30–33). Schulman et al. do not disclose a plurality of implantable sensing elements comprises a lactate sensing element measuring a parameter for blood lactate level and a pH level sensing element measuring a parameter for pH level. However, it is well known in the art for a plurality of implantable sensing elements to comprise a lactate sensing element measuring a parameter for blood lactate level and a pH level sensing element measuring a parameter for pH level to provide accurate and beneficial measurements to practitioners that assist them in making timely and precise decisions regarding a patient's specific medical condition. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Schulman et al. to include a plurality of implantable sensing elements comprises a lactate sensing element

measuring a parameter for blood lactate level and a pH level sensing element measuring a parameter for pH level to enhance a practitioner's ability to assess a patient's medical condition.

10. Schulman et al. disclose the essential features of the claimed invention as described above except for an output from at least one of the implantable sensing elements comprises reading an output from an implantable sensing element that responds to lactate (claims 5 and 27); and reading an output from at least one of the implantable sensing elements comprises reading an output from an implantable sensing element that responds to blood pressure (claims 7 and 29), potassium (claims 10 and 32), and pH (claims 11 and 33); and administering therapy comprises administering therapy for myocardial ischemia (claims 13, 34 and 44), myocardial infarction (claims 14, 35 and 45), angina (claims 15 and 36), sepsis (claims 18, 38 and 47), septic shock (claims 19 and 47), and a patient receiving extracorporeal membrane oxygenation (claims 20, 39 and 48), undergoing cardiac bypass (claims 21 and 40), and during dialysis (claims 22 and 41); administering therapy comprises adjusting a function (claims 16 and 46) and placement (claims 17, 37 and 46) of an implantable cardiovascular defibrillator disposed within a patient; classifying a severity of a condition of a patient based on an output read from at least one implantable sensing element (claim 23); a patient is in a surgical environment (claim 24) and an intensive care environment (claim 25). However, it is well known in the art for an output from at least one of the implantable sensing elements comprises reading an output from an implantable sensing element that responds to lactate; and reading an output from at least one of the implantable sensing elements comprises reading an output from an implantable sensing element that responds to blood pressure, potassium, and pH; and administering therapy comprises administering therapy for myocardial ischemia, myocardial infarction, angina (claims 15 and 36),

sepsis, septic shock, and a patient receiving extracorporeal membrane oxygenation, undergoing cardiac bypass, and during dialysis; administering therapy comprises adjusting a function and placement of an implantable cardiovascular defibrillator disposed within a patient; classifying a severity of a condition of a patient based on an output read from at least one implantable sensing element; a patient is in a surgical environment and an intensive care environment to provide a myriad of beneficial and appropriate therapies and diagnostics in an efficacious and expeditious manner in a variety of conditions and settings. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Schulman et al. to include the claimed limitations of claims 5, 7, 10, 11, 13–25, 27, 29, 32–41, and 44–48 to provide optimum therapies and diagnostics to patients in a timely manner under various conditions and settings.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TLS
July 28, 2006
28 July 2006

George Evanisko
Primary Exam
7/31/6